UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively, "Quincy"), and Mark Underwood[1] (collectively with Quincy, "Defendants") move pursuant to Fed. R. Civ. P. 56 for the entry of summary judgment in their favor. The grounds for this motion are set forth in the following memorandum of law. A separate Statement of Undisputed Material Facts ("SOF") has been contemporaneously filed in accordance with Rule 56.1 and is expressly incorporated herein.

PRELIMINARY STATEMENT

There is no dispute that Prevagen® is a dietary supplement. Plaintiffs plead it in their Complaint (Compl. ¶ 21), and the phrase "dietary supplement" (as well as the FDA disclaimer required for dietary supplements) is on the label of every single bottle of Prevagen that has been sold since its introduction to the market in 2007.

There also should be no dispute that marketing claims relating to dietary supplements must be substantiated by "competent and reliable scientific evidence" as that phrase is defined in the FTC's "Dietary Supplements: An Advertising Guide for Industry" (the "FTC Guidance"). The FTC's own website advises that the FTC Guidance provides marketers of dietary supplements—like Quincy—with the "how-tos" of substantiating marketing claims. The FTC Guidance also explains that "competent and reliable scientific evidence" is a "flexible" standard that considers the "totality of the evidence," which can include animal studies, *in vitro* studies, human clinical studies, and epidemiological evidence. There is no set number or type of study required by the FTC Guidance to substantiate dietary supplement marketing claims.

[1] Mr. Underwood has brought his own motion for partial summary judgment on jurisdictional grounds separately and without waiver of his rights to join Quincy's arguments set forth, and relief requested, herein. *See* Dkt Nos. 210, 211.

For unknown reasons, Plaintiffs now appear to be disavowing the regulatory framework for dietary supplements (which applies to both Plaintiffs' claims) that has been in place for more than twenty years. But they are attempting to change the rules *only as they apply to Quincy*. First, Plaintiffs are now urging the factually and legally untenable position that "[t]he term 'dietary supplement' has no legal meaning or significance." (SOF ¶ 80.) That statement is as preposterous as it is untrue. Putting aside that Plaintiffs admit in their Complaint that Prevagen is a dietary supplement, an admission relied upon by this Court, the FTC issued the FTC Guidance ***about dietary supplements*** in response to the ***Dietary Supplement*** Health Education Act of 1994 ("DSHEA"). The FTC Guidance was issued in order to answer the "many questions" DSHEA generated "about the FTC's approach ***to dietary supplement*** advertising." The phrase "dietary supplement" is therefore not only legally relevant but, in fact, *central* to this Action. According to the FTC's own guidance, manufacturers of ***dietary supplements***, such as Quincy, are unquestionably permitted to make "structure/function" claims relating to their products—subject to the substantiation standard the FTC set forth in the FTC Guidance.

Plaintiffs have also disavowed their own definition of competent and reliable scientific evidence. Ignoring the "flexible," "totality of the evidence" approach that the FTC has long endorsed in the FTC Guidance, Plaintiffs now argue that, "in this case," something more and never-before published is required; they baldly assert, with no explanation, that "in this case, competent and reliable scientific evidence means randomized, controlled human clinical studies ("RCTs") that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." (SOF ¶ 81.) This newly hatched drug-level RCT requirement has no basis under Section 5 of the FTC Act, DSHEA, the FTC Guidance, or any

other law or regulation otherwise applicable to dietary supplements. It is instead based solely on Plaintiffs' and their experts' say-so.

Quincy was never put on notice that Plaintiffs would advocate for such an arbitrary definition of "competent and reliable scientific evidence." Accordingly, it spent years accumulating scientific substantiation for the marketing claims being challenged in this Action (the "Challenged Claims") to ensure compliance with the "flexible" standard set forth in the FTC Guidance. This substantiation includes *in vitro*, animal, and human clinical studies on apoaequorin (an active ingredient in Prevagen). And although they were not required to conduct an RCT, Quincy went above and beyond what is typically done in the dietary supplement industry, and conducted the Madison Memory Study, a "gold standard" randomized double-blind, placebo-controlled study designed to examine the effects of apoaequorin on cognitive function in older adults. *See FTC v. Quincy Bioscience Holding Co., Inc.* 272 F. Supp. 3d 547, 553 (S.D.N.Y. 2017); (Compl. ¶ 28.). Quincy also relied on a vast body of scientific literature relating to the relationship between vitamin D (another active ingredient in Prevagen since 2016) and cognitive function, which lends further support to the Challenged Claims.

Defendants' experts (in the relevant fields of internal medicine, nutrition, neuroscience, dietary supplement substantiation, epidemiology, and biostatistics) evaluated this body of scientific substantiation in accordance with the "flexible," "totality of the evidence" approach set forth in the FTC Guidance and concluded that the Challenged Claims are supported by competent and reliable scientific evidence.

Plaintiffs' experts did not do the same. They did not even *consider* the relevant substantiation standard as set forth in the FTC Guidance, most likely because Plaintiffs failed to tell them that it existed, and were unfamiliar with the definition of "competent and reliable

scientific evidence" set forth therein or the regulatory requirements for dietary supplement products. They also *ignored* the majority of Quincy's scientific substantiation and instead focused almost exclusively on nit-picking aspects of the Madison Memory Study. They *assumed*—contrary to the FTC Guidance—that a drug-level RCT was required. Plaintiffs' and their experts' attempt to reinvent the standard through expert testimony should be rejected.

Even worse, Plaintiffs' expert reports do not support Plaintiffs' claims that Quincy did not adequately substantiate its marketing claims for Prevagen because those expert reports are nothing more than a re-packaging of the allegations in the Complaint regarding allegedly unreliable *post hoc* subgroup analyses. Despite being provided with the opportunity to develop evidence supporting their allegations, including nearly seven years of extensive investigational and litigation discovery, mountains of document discovery, and thirteen days of deposition testimony, Plaintiffs have failed to cure any of the deficiencies the Court previously identified with respect to their theory of liability. On the contrary, the undisputed record evidence disproves Plaintiffs' theories. Specifically, Plaintiffs and their experts (i) failed to show that the subgroup analyses relied on in the Madison Memory Study were, in fact, *post hoc*; (ii) failed to show that the subgroup analyses *actually resulted* in false positives as alleged in the Complaint (and Defendants' experts explained why they did not); and (iii) failed to rebut this Court's prior recognition (also confirmed by Defendants' experts) that subgroups are "widely used in the interpretation of data in the dietary supplement field." *Quincy Bioscience*, 272 F. Supp. 3d at 553. Thus, what was true in January 2017 when the Complaint was filed still rings true today: Plaintiffs' challenges do not "proceed[] beyond the theoretical." *Id.*

Plaintiffs have also failed to explain why "this case" warrants a different, unarticulated, standard than the one set forth in the FTC Guidance. Such an arbitrary change in the standard is

especially concerning because Quincy referred to and relied upon the FTC Guidance when it conceived the marketing claims at issue in this Action. Plaintiffs' attempt to impose a new, unpublished standard on Quincy—*retroactively and without notice*—violates Quincy's Due Process rights and should be rejected.

Independent of the substantiation issue, summary judgment is also warranted because Plaintiffs have failed to establish their entitlement to the relief they seek. As the Supreme Court recognized last year, the FTC has been improperly using Section 13(b) of the FTC Act to obtain monetary relief without proper statutory authorization for decades. *See AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1346-47 (2021). The FTC has glossed over other statutory limitations on injunctive relief in two material ways in this Action, both of which independently warrant summary judgment in Defendants' favor.

First, to obtain injunctive relief under Section 13(b), the FTC must establish that Quincy "is violating or is about to violate" the FTC Act. The FTC has failed to establish either here. It is undisputed that none of the Challenged Claims are currently being disseminated in the manner alleged in the Complaint (many of them were not even being disseminated when the Complaint was filed in 2017), and that Quincy is not "about to" violate the FTC Act. In 2020, Quincy entered into a nationwide class action settlement in *Collins v. Quincy Bioscience*, in which Quincy agreed to include one of two qualifiers when disseminating certain of the same marketing claims concerning Prevagen that are being challenged in this Action ("*Collins* Settlement"). Plaintiffs in this Action received notice of the *Collins* Settlement pursuant to the Class Action Fairness Act ("CAFA"), but sat mute at the final approval hearing and raised no objections. Thus, there is no danger that Quincy will resume dissemination of the marketing identified in the *Collins* Settlement (and challenged in this Complaint), barring the FTC's claim under Section 13(b) and both

Plaintiffs' claims under the general standard for injunctive relief set forth in *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953).

Second, after failing to either seek a temporary restraining order or a preliminary injunction at the outset of the case, the FTC cannot seek or obtain a permanent injunction. Section 13(b) states, in a proviso, that the FTC may only seek a permanent injunction in "proper cases" upon "proper proof." 15 U.S.C. § 53(b). Given the structure of the statute (and as recently noted by the Supreme Court), the FTC must first seek a preliminary injunction and only then, in a subset of "proper cases," may it seek a permanent injunction. *See AMG*, 141 S. Ct. at 1348. Here, the FTC conducted a full investigation into Quincy's marketing practices before filing this Action five years ago, yet inexplicably failed to seek either a temporary restraining order or preliminary injunction at any time. This tactical decision now precludes the FTC from seeking permanent injunctive relief and warrants summary judgment in Defendants' favor.

Finally, the NYAG's claims independently fail for a number of additional reasons. To the extent the NYAG is attempting to impose additional requirements for Prevagen's labeling and marketing beyond what is required by federal law, such claims are preempted and/or fail because of the safe harbor provision set forth in the New York General Business Law. And the NYAG has all but conceded that its claim for restitution is barred by the *Collins* Settlement. Allowing the NYAG's claim to proceed would not only result in a double recovery that CAFA was designed to avoid, but would undermine the finality of any future class action settlement.

For all of these reasons, as set forth more fully herein, Defendants respectfully request that this Court enter summary judgment in their favor and dismiss all of the claims brought by Plaintiffs with prejudice.

SUMMARY OF MATERIAL FACTS

A. Background on Prevagen

Prevagen® is a dietary supplement. (SOF ¶ 11.) The Prevagen line of products include Prevagen Regular Strength, Extra Strength Prevagen, and Prevagen Professional. (SOF ¶ 18.) Apoaequorin, one of Prevagen's active ingredients, is a calcium-binding protein derived from aequorin, which was originally discovered in the aequorea victoria jellyfish. (SOF ¶ 12.) In or around 2016, Prevagen Products were reformulated to include 50 micrograms of vitamin D3 (in addition to apoaequorin) per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D. (SOF ¶ 15.)

Prevagen's target market is, and always has been, healthy, older community dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process. (SOF ¶ 16.)

B. The Dietary Supplement Health & Education Act of 1994 & the FTC Guidance

In recognition of the health benefits of dietary supplements, Congress enacted DSHEA, which amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to establish standards with respect to dietary supplements and to create a new category of marketing claims for dietary supplements called "structure/function" claims. (SOF ¶¶ 56-57.)

In January 2002, the United States Food and Drug Administration ("FDA") issued the "Small Entity Compliance Guide on Structure/Function Claims." (SOF ¶ 58.) Examples of "structure/function" claims include those associated with "mild memory loss associated with aging." (*Id.*, Graham Decl. Ex. J at 6.) "Structure/function" claims for dietary supplements can be made without prior review or approval by the FDA. (*Id.*, Graham Decl. Ex. J at 1—2.)

Following the passage of DSHEA, the FTC issued the FTC Guidance to answer questions about the FTC's approach to dietary supplement advertising. (SOF ¶ 59., Graham Decl. Ex. F at

1.) The FTC Guidance, which has been made available since at least 2001, states that dietary supplement advertising "must be truthful, not misleading, and substantiated" and is directed to dietary supplement manufacturers to "explain[] the how-tos of making sure your claims have appropriate scientific support." (SOF ¶¶ 60, 61, 64.) The FTC states that the standard is "flexible," requiring only that advertisers of dietary supplements possess "competent and reliable scientific evidence" to substantiate their claims. (SOF ¶ 65.) The FTC Guidance defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area[.]" (SOF ¶ 66.) "There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration." (SOF ¶ 67, FTC Guidance at 9.) Randomized human clinical trials are not required under the FTC Guidance. (SOF ¶ 68.) Rather, the FTC Guidance states that the FTC will consider all forms of competent and reliable scientific research when evaluating substantiation, including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and all forms of human studies. (SOF ¶ 69.) Finally, the FTC Guidance states that "[s]tudies cannot be evaluated in isolation," and that the FTC looks to the "totality of the evidence" in evaluating substantiation. (SOF ¶ 71.)

Quincy has relied upon—and continues to rely upon—the FTC Guidance when drafting its marketing claims for Prevagen. (SOF ¶ 74.) Quincy even engaged outside counsel to review the scientific evidence and confirm that the labels and advertisements for Prevagen complied with DSHEA and the FTC Guidance. (SOF ¶ 75.) In addition, to comply with FDA regulations and DSHEA, each Prevagen marketing piece and label includes a disclaimer that states: "This product is not intended to diagnose, treat, cure or prevent any disease." (SOF ¶ 14.)

C. The Challenged Claims

In this Action, Plaintiffs allege that the following marketing claims for Prevagen are false and misleading: (1) improves memory; (2) improves memory within 90 days; (3) reduces memory problems associated with aging; (4) provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking; and (5) is clinically shown to have such effects (the "Challenged Claims"). (Compl. ¶¶ 36, 39, 42, 44.) None of these advertising claims are currently being disseminated in the manner alleged in the Complaint. (SOF ¶ 26.)

D. Prevagen's Marketing is Supported by Competent and Reliable Scientific Evidence

Quincy has dedicated years researching and accumulating substantiation relating to apoaequorin's beneficial effect on cognitive function before bringing Prevagen to market. After conducting studies demonstrating that apoaequorin is neuroprotective when administered to the brain before an ischemic insult (SOF ¶ 84), Quincy moved on to other animal and human studies, which provide further evidence to support and substantiate the Challenged Claims.

1. Animal Studies

Beginning in or about November 2004, and continuing to date, the Neurophysiology and Behavior Laboratory, University of Wisconsin-Milwaukee conducted, and continues to conduct, numerous studies on apoaequorin in animal models. (SOF ¶ 83.) The animal studies conducted by the University of Wisconsin-Milwaukee consistently reported that apoaequorin provides a cognitive benefit, including neuroprotective effects. (SOF ¶ 84.) Certain results of animal studies performed at the University of Wisconsin-Milwaukee's laboratory were published in a peer-reviewed journal. (SOF ¶ 85; Detert JA, et al., *Pretreatment with apoaequorin protects hippocampal CA1 neurons from oxygen-glucose deprivation*, PLos One, 2013; 8(11):e790002.)

Quincy has also sponsored research on apoaequorin through canine models, which reported that apoaequorin provides beneficial cognitive effects. (SOF ¶¶ 86.) Results from Quincy's canine

studies were also published in a peer-reviewed journal. (SOF ¶ 87, N. Milgram et al., *A novel mechanism for cognitive enhancement in aged dogs with the use of a calcium-buffering protein*, Journal of Veterinary Behavior 10 (2015) 217-222.)

2. Open Label Human Clinical Research on Prevagen

Quincy next conducted open label human clinical research to assess the impact of apoaequorin on general health and quality of life. (SOF ¶ 89.) Between May 2008 and January 2009, Quincy conducted an open label clinical trial consisting of approximately 55 adult participants to assess the impact of apoaequorin on general health and quality of life, including cognitive function (the "Open Label Trial"). (SOF ¶ 89.) Participants in the Open Label Trial received 10 mg of apoaequorin per day over 90 days and responded to a battery of questions from the SF-36 Survey, a standardized measure of health status, and ERA-38 Survey, the purpose of which is to measure changes in expectations regarding aging among older adults. (SOF ¶ 90.) The Open Label Trial reported a statistically significant benefit on questions related to cognitive function, fatigue, sleep, and general health for participants. (SOF ¶ 91.)

Further, in or about 2014, Sunsho Pharmaceuticals, Ltd. ("Sunsho"), conducted a clinical trial testing the efficacy of Prevagen on cognitive functioning and quality of sleep. Fifteen men and women aged forty and above were administered one capsule of Prevagen every morning for 30 days. (SOF ¶ 92.) The Sunsho trial noted that, after 30 days of intake of Prevagen, there was "a confirmed rise in the score which showed a statistically significant difference from the score before intake" and that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (SOF ¶ 93.)

3. The Madison Memory Study

Quincy also conducted the Madison Memory Study ("MMS"), a 90-day randomized, double-blind, placebo-controlled study designed "to determine whether Prevagen with

apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." (SOF ¶ 96; Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, at 1 (Aug. 1, 2016); Compl. ¶ 28); *Quincy Bioscience*, 272 F. Supp. 3d at 553.

For the Madison Memory Study, 218 adults aged 40 to 95, each with self-reported memory difficulties, were randomly assigned to receive either apoaequorin capsules or placebos, and were instructed to take one capsule per day. (SOF ¶ 97.) Examiners obtained a baseline cognitive score for each participant using an eight-question screening tool called AD8, used to differentiate between adults facing normal cognitive aging and those with early signs of dementia. (SOF ¶ 98.) AD8 scores of 0 to 2 are generally considered reflective of normal aging or "very mild" cognitive impairment—i.e, healthy, older adults. (SOF ¶ 99.) While Quincy did not exclude any participants based on AD8 score, it planned to recruit, and did in fact recruit, 100 participants in the Madison Memory Study who reported an AD8 score of 0-2 because that score is consistent with community dwelling adults and is consistent with the intended study population. (SOF ¶¶ 100—104.)

On days zero, eight, 30, 60, and 90, participants completed nine quantitative computerized tests designed to measure several areas of cognitive function. (SOF ¶ 105.) The tests were selected from the Cogstate Research Battery—a "widely used neuropsychological battery of computerized cognitive tests"—which measured a variety of aspects of cognitive function, including verbal learning, memory, executive function, visual learning, psychomotor function, and working memory. (SOF ¶ 106; Compl. Ex. C(12).) At the end of 90 days, Quincy analyzed and reported on the data from all 218 participants, as well as a number of smaller groups of participants,

including the AD8 0-1 and AD8 0-2 study groups that matched the target study population. (SOF ¶ 108.)[2]

The Madison Memory Study demonstrated statistically significant results in the targeted study groups, which "contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging." (SOF ¶ 109.) Specifically, results showed that participants in the treatment group with AD8 scores of 0-2 showed statistically significant improvements as compared to placebo recipients on three different Cogstate tests (Groton Maze Learning, One Card Learning, and Identification) and outperformed the placebo group on four additional tests. (SOF ¶ 110.) Participants in the treatment group with AD8 scores of 0-1 also experienced statistically significant improvements as compared to placebo recipients on three Cogstate tests (Groton Maze Recall, Detection, and One Card Learning) and outperformed the placebo group on four additional tests. (SOF ¶ 111.) The placebo group did not show any statistically significant improvement as compared to the treatment group on any of the Cogstate tasks in the AD8 0-1 and AD 0-2 subgroups. (SOF ¶ 112.)

Because Prevagen is "intended for healthy, non-demented individuals," results from the AD8 0-1 and AD8 0-2 subgroups were considered "the most relevant to the efficacy of the product." (SOF ¶ 113.) Accordingly, the Madison Memory Study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either

[2] While Plaintiffs allege, and their experts assume, that the AD8 0-1 and AD8 0-2 subgroups were "post hoc," it is undisputed that Quincy decided to analyze participant data based on AD8 scores before the Madison Memory Study commenced. (SOF ¶ 107.) Plaintiffs' experts who reviewed the Madison Memory Study admitted that they had no idea when these "subgroup" analyses were planned, when they were conducted, or in what order they were conducted. (SOF ¶¶ 139, 141—142.) In any event, subgroup analyses, and even *post hoc* subgroup analyses, are common in the scientific community and published in peer-reviewed journals. (SOF ¶ 143.)

normal cognitive aging or very mild impairment, as determined by AD8 screening." (SOF ¶ 114, MMS at 8; Compl. ¶ 29 (acknowledging "positive findings").)

4. Vitamin D

In addition to the research on apoaequorin, there is a vast body of scientific literature supporting a relationship between vitamin D, which has been part of Prevagen's formulation since 2016, and improved cognitive function. (SOF ¶ 118.) This evidence includes RCTs, meta-analyses, cross-sectional studies, and prospective studies that demonstrate beneficial associations between higher vitamin D *intake* and cognitive function, as well as higher vitamin D *levels* and cognitive function. (SOF ¶ 118.)

E. The Parties' Expert Reports

Quincy's experts with specialties in the relevant fields of internal medicine, nutrition, neuroscience, dietary supplement substantiation, epidemiology, and biostatistics, evaluated Quincy's body of scientific substantiation in accordance with the flexible, totality of the evidence approach set forth in the FTC Guidance, and all concluded that the Challenged Claims are supported by competent and reliable scientific evidence. (SOF ¶¶ 121—122.) Indeed, Quincy's experts have confirmed that Quincy has amassed significantly more scientific substantiation than what is typically seen in the dietary supplement industry. (SOF ¶ 123.)

Plaintiffs' experts did not review, nor did they attempt to apply, any aspect of the FTC Guidance in forming their opinions in this Action. That is most likely because they were not aware that the FTC Guidance existed. (SOF ¶¶ 125—127, Berg Tr. 34:14-16 (Q: Are you familiar with the FTC's advertising guide for dietary supplements? A: I am not.); Sano Tr. 39:21-24 (Q: Are you familiar with the document titled "Dietary Supplements and Advertising Guide for Industry?" A: I am not.); Wittes Tr. 52:18—53:14 (Q: Have you ever seen the document marked JW-4 [the FTC Guidance] before? A: No, I have not.).) They also were not familiar with the "competent and

reliable scientific evidence" standard that the FTC applies to dietary supplement marketing claims. (SOF ¶¶ 128-30, Berg Tr. 34:11-16; 90:6-9 (Q: Have you ever heard of the phrase "competent and reliable scientific evidence"? A: I've heard the phrase. I don't know its technical meaning.); Sano Tr. 37:24—38:11, 39:12—41:8 (Q: Have you heard that phrase, in its exact form, "competent and reliable scientific evidence," prior to being retained for this case? A: I can't say that I've seen the phrase specifically. I can say that I've heard both "competent" and "reliable" spoken of in the field.); Wittes Tr. 35:19—37:18 (Q: Dr. Wittes, have you ever heard of the phrase "competent and reliable scientific evidence"? A: I have never heard that phrase, no.).) Instead, Plaintiffs' experts assumed that an RCT was required, and focused their analysis on the Madison Memory Study.[3] Finally, Plaintiffs' experts did not review any marketing material for Prevagen, have no experience in marketing, offered no opinion relating to how consumers would interpret or perceive the Challenged Claims, and therefore offer no opinion as to whether the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstance." (SOF ¶ 131.) In fact, Plaintiffs proffered no expert testimony on consumer perception at all. (SOF ¶¶ 132—36.)

F. The *Collins* Settlement

Quincy stopped disseminating many of the specific marketing claims and advertisements being challenged in this Action before Plaintiffs even filed their Complaint in 2017. (SOF ¶¶ 26—38.) Further, on June 22, 2020, Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman entered into a nationwide class action settlement in the matter captioned *Collins, et al. v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla.), resolving a series of class actions

[3] Plaintiffs did not provide Dr. Wittes with documents relating to any of Quincy's substantiation other than the Madison Memory Study and Dr. Sano reviewed Quincy's animal, *in vitro,* and open label studies on apoaequorin, but considered them to be irrelevant. (SOF ¶¶ 137—138.)

challenging the same marketing claims challenged in this Action. (SOF ¶ 39, *Collins* ECF No. 143-1.)

As part of the *Collins* Settlement, Quincy agreed to include in the marketing relating to Prevagen one of two statements (referred to herein as the "Qualifiers") with the Challenged Claims:

i. Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.

ii. Based on results from two subgroups of individuals who participated in a randomized double blind placebo controlled clinical study. Participants in the two subgroups were cognitively normal or mildly impaired. This product is not intended to diagnose, treat, cure, or prevent any disease.

(SOF ¶ 45.)

Plaintiffs were notified of the *Collins* Settlement and were afforded an opportunity to object, but chose not to voice an objection when they appeared at the final approval hearing. (SOF ¶ 46.)[4] Instead, Plaintiffs filed a letter on the *Collins* docket stating that their lack of objection to the settlement "should not be construed . . . as approval or disapproval." (SOF ¶ 47.)

Nevertheless, the United States District Court for the Southern District of Florida found the terms of the *Collins* Settlement to be "fair, reasonable, and adequate," and incorporated them into a Final Judgment and Order. (SOF ¶¶ 41—42.) Following the entry of the Final Order and Judgment with respect to the *Collins* Settlement, Prevagen, Inc. incorporated the Qualifiers into all new advertising, labeling and marketing materials for Prevagen that made the marketing claims identified in the *Collins* Settlement. (SOF ¶ 49.) None of the marketing claims identified in the

[4] In fact, despite a comprehensive notice plan, only one objection to the Class Action Settlement was filed by a serial objector. The *Collins* Court dismissed that objection. (SOF ¶ 48, *Collins* ECF Nos. 195 and 162-2.)

Collins Settlement are currently being used in the marketplace in the form challenged in the Complaint, as they all contain one of the Qualifiers. (SOF ¶ 50.)

ARGUMENT

I. LEGAL STANDARD

a. Summary Judgment

Summary judgment is appropriate where there are no issues of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-50 (1986). A motion for summary judgment should be granted if "no reasonable trier of fact could find in favor of the nonmoving party." *Allen v. Coughlin*, 64 F.3d 77, 79 (2d Cir. 1995) (citation omitted).

b. The FTC Act

Section 13(b) of the Federal Trade Commission Act authorizes the FTC to obtain a temporary restraining order or preliminary injunction and, "in proper cases," a "permanent injunction," in federal court against "any person, partnership, or corporation" that it believes "is violating, or is about to violate, any provision of law" that the FTC has the power to enforce. 15 U.S.C. § 53(b). Here, the FTC seeks to enjoin alleged violations of Sections 5 and 12 of the FTC Act. Section 5 requires proof of "(1) a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3) . . . is material." *FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 303 (S.D.N.Y. 2008) (citation omitted). Likewise, to prove "false advertising" under Section 12 of the FTC Act, the FTC must show that Quincy's advertisements are "misleading in a material respect." 15 U.S.C. §§ 52(a)(2), 55(a)(1); *see also Quincy Bioscience*, 272 F. Supp. 3d at 552-53.

c. The NYAG's Claims

To prove their allegations under General Business Law § 349, the New York Attorney General ("NYAG") must establish that Defendants "engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (2012) (citation omitted). GBL §§ 349 and 350 "comprise a 'mini' [FTC] Act, having been modeled on that analogous federal statute." *Braynina v. TJX Cos., Inc.*, No. 15 CIV. 5897, 2016 WL 5374134, at *6 (S.D.N.Y. Sept. 26, 2016) (alteration in original) (quoting *People ex rel. Spitzer v. Applied Card Sys., Inc.*, 11 N.Y.3d 105, 120 (2008)). Indeed, Sections 349 and 350 were "enacted 'to follow in the steps of the [FTC] with respect to the interpretation of deceptive acts and practices outlawed in Section 5 of the [FTC] Act.'" *Id.* (*citing State ex rel. Lefkowitz v. Colo. State Christian Coll. of Church of Inner Power, Inc.*, 346 N.Y.S.2d 482, 486-87 (Sup. Ct., N.Y. County 1973)).

New York Executive Law § 63(12) further provides that:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . to the supreme court of the state of New York . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages . . . .

N.Y. Exec. Law § 63(12). Section 63(12) "does not create an independent cause of action" but, rather, "is only a mechanism by which a petitioner may show that injunctive relief and restitution are proper in the event that the petitioner establishes that a respondent violated other statutes." *People ex rel. Schneiderman v. One Source Networking, Inc.*, 3 N.Y.S.3d 505, 508 (4th Dep't 2015).

For the reasons set forth below, all of Plaintiffs' claims are governed by the "competent and reliable scientific evidence" standard of substantiation set forth in the FTC Guidance.

II. THE CHALLENGED CLAIMS ARE SUBSTANTIATED STRUCTURE/ FUNCTION CLAIMS

a. Summary Judgment is Warranted Because Quincy Was Only Required to Substantiate its Marketing Claims Through Competent and Reliable Scientific Evidence, A Standard Much More Flexible than Plaintiffs and Their Experts Seek to Impose

i. Regulatory Background: DSHEA and the FTC Guidance

In recognition of the health benefits of dietary supplements, Congress enacted DSHEA to ensure that dietary supplements could be marketed and sold without the stringent requirements that are placed on drugs. S. Rep. 103-410, at 24 (1994) ("[T]he scientific evidence supporting a claim should not be held to the same standard used in evaluating new drug applications."); S. 784, 103rd Cong. § 2(b)(2)(B) (1994) ("It is the purpose of [the DSHEA] to . . . clarify that . . . dietary supplements should not be regulated as drugs."); 21 U.S.C. § 321(g)(1). DSHEA created a new category of marketing claims called structure/function claims, which "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 U.S.C. § 343(r)(6)(A). Structure function claims must be "truthful and not misleading" and, unlike drug claims, do not require the prior approval of FDA. *See* 21 U.S.C. §§ 321(g)(1), 343(r)(6).

In January 2002, FDA issued the "Small Entity Compliance Guide on Structure/Function Claims" (the "Compliance Guide"), which "restate[s] in plain language the legal requirements set forth in a regulation concerning labeling for dietary supplements." (SOF ¶ 58, Graham Decl. Ex. J. at 1.) The Compliance Guide confirms that structure/function claims can be made for dietary supplements without prior FDA review or approval. Thus, *as long as a dietary supplement is not marketed as a drug, it is not regulated like a drug*. *See* 21 U.S.C. § 343(r)(6); *see also* 21 U.S.C. §§ 321(g)(1).

Because DSHEA does not elaborate on what is required for a claim to be considered "truthful and not misleading," in 1998, the FTC issued the FTC Guidance to answer the "many

questions" DSHEA generated "about the FTC's approach to dietary supplement advertising." (SOF ¶ 62, FTC Guidance at 1); *see United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015) (because "DSHEA does not specify what substantiation is necessary to render a claim 'truthful and not misleading,'" the FTC subsequently issued the FTC Guidance to shed further light on the meaning of "competent and reliable scientific evidence."). The FTC Guidance reiterates DSHEA's requirement that structure/function claims be "truthful, not misleading, and substantiated," and is specifically directed to dietary supplement manufacturers to "explain[] the how-tos of making sure your claims have appropriate scientific support." (SOF ¶¶ 61, 64.)

The FTC Guidance explains that dietary supplement marketing claims must be substantiated by "competent and reliable scientific evidence," which is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area[.]" (SOF ¶¶ 65, 66.) The FTC Guidance makes clear that this standard is "sufficiently flexible to ensure that consumers have access to information about emerging areas of science," and contains, among others, the following relevant provisions:

- There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. (SOF ¶ 67; FTC Guidance at 8-9.)
- The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation, including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and human studies. (SOF ¶ 69; FTC Guidance at 10.)
- There is no requirement that a claim regarding a dietary supplement be supported by any specific number of studies. (SOF ¶ 72; FTC Guidance at 10.)
- There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. (SOF ¶ 73; FTC Guidance at 12.)
- Studies cannot be evaluated in isolation. (SOF ¶ 73; FTC Guidance at 14.)

- Randomized human clinical trials are not required. (SOF ¶ 68; FTC Guidance at 9-18.); *see Bayer*, 2015 WL 5822595, at *3-4.

ii. The FTC Guidance Sets Forth the Applicable Substantiation Standard For Dietary Supplement Advertising Claims

The FTC is now attempting to distance itself from its own Guidance despite recognition from courts around the country that the "competent and reliable scientific evidence" standard articulated in the FTC Guidance is the governing standard for substantiation of dietary supplement structure/function claims. For example, in *Bayer*, the federal court in the District of New Jersey looked to the FTC Guidance to resolve the FTC's claims that Bayer had violated a prior consent decree in which it agreed not to make marketing claims without supporting "competent and reliable scientific evidence,"[5] and made three key observations. First, the court found that the FTC Guidance "makes clear" that the substantiation standard for dietary supplements "is not the drug standard" and that "[r]andomized clinical trials are not required." 2015 WL 5822595, at *3.[6] Second, the court held that the FTC Guidance sets forth a "totality of the evidence" standard, that looks to the "surrounding body of evidence" to determine the "type, amount and quality of evidence" required to substantiate a claim. *Id.* at *4. And third, the court found that "studies on the precise formula used in the advertised product are not required," and that "it can be 'appropriate to extrapolate from the research to the claimed effect.'" *Id.*

With these principles in mind, the court reviewed Bayer's proffered substantiation for the vitamins and dietary supplements at issue, which included studies conducted on the species of

[5] The consent decree at issue defined "competent and reliable scientific evidence" in the same manner defined in the Guidance. 2015 WL 5822595, at *3.

[6] FDA agrees in its own guidance with respect to dietary supplements that randomized clinical trials are not required, "recognizing that randomized, controlled clinical trials for dietary supplements may not be 'possible, practical, or ethical.'" *Bayer Corp.*, 2015 WL 5822595, at *4 (citing FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act*).

bacteria in the product, but did not include a randomized clinical trial on the product itself. *Id.* at *7-8. The FTC's expert opined that "'competent and reliable scientific evidence' could only be met through 'human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the populations at which claims are directed; and (4) use validated methods and appropriate statistical models to assess 'outcomes.'" *Id.* at *4. The FTC's expert created this standard completely on his own; he did not review or rely on the FTC Guidance, had not heard of DSHEA, and was not even aware of the "regulatory distinction between 'structure function' claims and disease claims." *Id.* at *10. In fact, he conceded that his proposed study design "was not specific to probiotics or dietary supplements," and that it would be "basically appropriate for any situation in which you want to obtain reliable results." *Id.* at *9.

The court rejected the FTC's position as inconsistent with the FTC Guidance and found Bayer's claims to be supported by "competent and reliable scientific evidence." *Id.* at *14-19. Notably, the court relied on the fact that (as here) the FTC's expert had not reviewed the FTC Guidance, did not rely on the FTC Guidance, was not familiar with (and had not even heard of) DSHEA, and was unaware of any distinction between structure/function and disease claims. *Id*. Moreover, the court found that the FTC had "no evidence of any law, regulation or guidance that would have provided notice to Bayer that" RCTs, and particularly the specific RCT design contemplated by the FTC's expert, would be required to substantiate the marketing claims at issue. *Id*. The court ultimately held that the FTC could not satisfy its burden of proof by relying on "one expert who seems to require a higher-level" of substantiation than required by the FTC Guidance. *Id.* at *18.

A federal court reached a similar result in *Basic Research, LLC v. Federal Trade Commission*, concluding that structure/function claims relating to the defendant's weight loss supplements were supported by competent and reliable scientific evidence under a prior Decision and Order that used the same flexible definition set forth in the FTC Guidance. 2014 WL 12596497, at *1 (D. Utah Nov. 25, 2014).[7] The defendant's expert reviewed all of the available evidence and found the claims to be adequately substantiated. *Id.* at *3. The FTC's expert, however, ignored the totality of the evidence and instead measured the proffered substantiation against the "ideal" or "Gold Standard" of an RCT that has been published in a peer-reviewed journal and confirmed by additional investigations at independent research institutions. *Id*. The court recognized that, while a disagreement among experts would "typically . . . preclude summary judgment for either party because the differing opinions address material issues that are at the heart of th[e] case," summary judgment ***was appropriate*** because the FTC "failed to apply the correct standard when evaluating [the defendant's] evidence." *Id.* at *10-11. Indeed, the court held that "the FTC must do more than present an expert who simply disagrees with the scientific literature upon which [the defendant] relied. The FTC must present evidence that shows how" the defendant's research fails to constitute competent and reliable scientific evidence. *Id.* at *10. Because the FTC had failed to do so, the court granted summary judgment in defendant's favor.

Finally, in *Federal Trade Commission v. Garden of Life, Inc.*, the FTC moved for an order to show cause why dietary supplement manufacturer Garden of Life ("GOL") should not be held in contempt of a Stipulated Final Order and Permanent Injunction that barred GOL from making certain representations in its advertisements unless they were supported by "competent and reliable

[7] Like in *Bayer*, *Basic Research* involved allegations that the defendant had violated a prior Decision and Order requiring "competent and reliable scientific evidence" for certain claims. That Decision and Order defined "competent and reliable scientific evidence" identically with the Guidance. *Id.* at *9.

scientific evidence" as defined in the Guidance. 516 Fed. App'x 852, 854 (11th Cir. 2013).[8] The FTC's expert argued that the studies GOL relied upon were "insufficiently rigorous" to the extent they examined what he believed to be irrelevant populations. *Id.* at 856. GOL, in turn, submitted its own expert who reviewed the studies at issue, disagreed with the FTC's expert, and concluded that the challenged marketing claims "had sufficient scientific support" as required by the order (and therefore the FTC Guidance). *Id.* The Eleventh Circuit rejected the FTC's attempt to hold GOL to a higher substantiation standard: "to find that GOL violated the terms of the Order solely because another well-respected expert defines 'brain development' differently or disagrees with certain aspects of a study's 'trial design' would require this Court to read additional requirements into" the competent and reliable scientific evidence standard. *Id.* (citation omitted).

These cases confirm that the appropriate standard to be applied in this case—to both Plaintiffs' claims—is the "competent and reliable scientific evidence" set forth in the FTC Guidance. (SOF ¶ 81, Response to RFA No. 8 (admitting the "competent and reliable scientific evidence" standard applies to the dietary supplement advertising claims); *see also* Section D, *supra*.)

iii. The Challenged Claims Are Substantiated by Competent and Reliable Scientific Evidence

Quincy has amassed "significantly more" substantiation than what is typically seen in the dietary supplement industry. (SOF ¶ 123.) A series of animal and *in vitro* studies, some of which have been published in a peer-reviewed journal, demonstrate that apoaequorin provides a cognitive benefit, including neuroprotective effects. (SOF ¶¶ 83—87.) Results from Quincy's canine studies are particularly persuasive given that dogs provide a natural animal model for mild

[8] The order at issue in *GOL* defined "competent and reliable scientific evidence" in a manner that was consistent with the Guidance. *Compare* (FTC *Guidance* at 9), *with Garden of Life*, 516 Fed. App'x at 854.

cognitive dysfunction in humans. (SOF ¶ 88.) Open label human clinical trials on apoaequorin also demonstrated statistically significant benefits on cognitive function. (SOF ¶¶ 91, 93.)

A wealth of scientific literature, including RCTs, meta-analyses, cross-sectional studies, and prospective studies, demonstrate beneficial associations between higher vitamin D *intake* and cognitive function, as well as higher vitamin D *levels* and cognitive function. (SOF ¶¶ 118, 119.) Given the prevalence of vitamin D deficiency in adults in the United States and the low levels of vitamin D being consumed by most people, this evidence supplements the research discussed above on apoaequorin and confirms that the Challenged Claims are supported by competent and reliable scientific evidence as set forth in the FTC Guidance. (SOF ¶¶ 117, 120.)

Finally, despite that randomized clinical trials are not required to substantiate structure/function claims for dietary supplement products, Quincy went above and beyond and conducted the Madison Memory Study—a 90-day randomized, double-blind, placebo controlled trial—to determine whether Prevagen improves quantitative measures of cognitive in community dwelling, older adults. (SOF ¶¶ 68, 96); *Quincy Bioscience*, 272 F. Supp. 3d at 550-51. As discussed above, the Madison Memory Study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairments" as determined by AD8 screening. (SOF ¶ 114.)

Defendants' experts have evaluated this substantiation in accordance with the flexible, "totality of the evidence" approach set forth in the FTC Guidance, and concluded that the Challenged Claims are substantiated. (SOF ¶ 122.)

iv. Plaintiffs' and Plaintiffs' Experts Ignored the Relevant Substantiation Standard

For reasons unknown, Plaintiffs have bent over backwards to distance themselves from DSHEA and from their own definition of "competent and reliable scientific evidence" as set forth

in the FTC Guidance. For example, in written discovery, Plaintiffs have made the untenable assertion that "[t]he term 'dietary supplement' has no legal meaning or significance;" and that *"[a]s applied to the claims challenged in this case*, competent and reliable scientific evidence means randomized, controlled human clinical studies ('RCTs') that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." (SOF ¶ 81 (emphasis added).) Plaintiffs' assertion is contrary to the FTC Guidance and is directly contradicted by both the passage of DSHEA itself, which was designed to ensure that dietary supplement products could be marketed and sold *without* the stringent RCT requirements that are placed on drugs, *and* by the FTC Guidance, which was issued directly in response to DSHEA to help *dietary supplement* companies ensure that their advertising claims comply with DSHEA. (SOF ¶¶ 61—63.)

Of particular relevance here, Plaintiffs did not share the FTC Guidance with their experts, none of them reviewed it, and none of them had any understanding of the governing "competent and reliable scientific evidence" standard. In fact, they had never even heard of this standard as of the time they signed their respective expert reports. (SOF ¶¶ 124—130, Berg Tr. 34:8-16; 90:6-9; Wittes Tr. 35:19—37:18; Sano Tr. 37:18—38:7; Sano Decl. ¶¶ 2—7.) Plaintiffs' experts also failed to *consider* let alone *apply* DSHEA, the FTC Guidance, or any other law or regulation in forming their opinions or drafting their expert reports. (SOF ¶ 124, Sano Tr. 36:16-21, 39:21—41:13; Wittes Tr. 33:6-9, 53:7—54:13; Berg Tr. 34:11-16.) Specifically, Dr. Sano testified she was not aware that the FTC Guidance had its own definition of "competent and reliable scientific evidence" for dietary supplements and did not even know that Prevagen was a dietary supplement. (SOF ¶ 129, Sano Tr. 39:12—41:8.) Dr. Wittes could not recall if she ever heard the phrase "competent and reliable scientific evidence," could not explain what the phrase meant to her, and

testified that she "ha[s] no idea where that phrase comes from with respect to dietary supplements." (SOF ¶ 130, Wittes Tr. 35:19—37:18). And Dr. Berg testified that he did not know the "technical" definition of dietary supplements, was not familiar with DSHEA, was not familiar with the FTC Guidance, and, while he had heard the phrase "competent and reliable scientific evidence," he testified that he did not know "its technical meaning." (SOF ¶¶ 124, 128, Berg Tr. 34:8-16, 90:6-9.)

Instead of evaluating Quincy's scientific substantiation under the "flexible," "totality of the evidence" standard set forth in the FTC's 30-page FTC Guidance document, Plaintiffs rely on a new, heightened standard, nowhere to be found in the FTC Guidance: "[a]s *applied to the claims challenged in this case*, competent and reliable scientific evidence means randomized, controlled human clinical studies ("RCTs") that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." (SOF ¶ 81.) The FTC's brand new, drug-level RCT "requirement" is not codified in DSHEA, nor is it discussed—let alone set forth—in any law or regulation. It certainly is not consistent with the "flexible" approach set forth in its own Guidance, which remains on the FTC's website to this day. Most importantly, Plaintiffs have failed to explain why "this case" is different from others, or why it warrants a different definition with respect to the "competent and reliable scientific evidence" than the FTC has endorsed and published and that Quincy relied upon in drafting the Challenged Claims. (SOF ¶ 74.)

Plaintiffs have adopted the same flawed approach here that the FTC adopted—and courts flatly rejected—in *Bayer*, *Basic Research*, and *Garden of Life*. Like in those cases, none of Plaintiffs' experts reviewed, much less applied, the "competent and reliable scientific evidence" standard set forth in the FTC Guidance and instead assumed, incorrectly, that a drug-level RCT

was required to substantiate the Challenged Claims. Plaintiffs' attempt to "reinvent [the] standard through expert testimony" should be rejected and summary judgment should be entered in Quincy's favor. *Bayer*, 2015 WL 5822595 at *14.

b. Even if Held to a Higher Standard Beyond the Guidance, Plaintiffs' "Criticisms" of the Madison Memory Study Are Unsupported By the Record

Even if the Court were to disregard the battery of *in vitro*, animal, and open label studies in the record and *assume* that a RCT is required to substantiate the Challenged Claims (it is not), Quincy has one. Long before this Action was filed, and despite not being required to do so, Quincy conducted a RCT—the Madison Memory Study—a randomized, double-blind, placebo-controlled human clinical trial, which showed that Prevagen improved aspects of cognitive function in older participants with either normal cognitive aging or very mild impairments, as determined by AD8 screening. (SOF ¶ 96.)

But even this "gold standard" trial design is not enough to satisfy Plaintiffs, who tasked their experts with nitpicking certain aspects of the design, conduct, and interpretation of the Madison Memory Study based on their own unsupported assumptions about the study. This approach is wholly inconsistent with the FTC Guidance, which advises that there is no set protocol for how to conduct research that will be acceptable under the FTC's substantiation doctrine. (SOF ¶ 73); *see Garden of Life*, 516 Fed. App'x at 856 (simply because an expert "disagrees with certain aspects of a study's 'trial design'" does not support finding that defendant's claims are unsubstantiated); *Bayer*, 2015 WL 5822595, at *16 (rejecting FTC's assertion that a RCT must follow "a specific study design or protocol"). In any event, and despite these efforts, Plaintiffs' experts came up empty and the so-called "flaws" they identified are either unsupported by the record, inconsistent with sound scientific method, or both. As this Court previously held nearly five years ago, "[i]t is common ground that the Madison Memory Study followed normal well-

accepted procedures, conducted a 'gold standard' double blind, placebo controlled human clinical study using objective outcome measures" and therefore "plaintiffs' challenge never proceeds beyond the theoretical." *Quincy Bioscience*, 272 F. Supp. 3d at 553. Despite a mountain of discovery, including thirteen depositions, Plaintiffs have failed to move the needle any further from where it was on September 28, 2017 when their Complaint was first dismissed. *Id.*; (SOF ¶ 151.)

Plaintiffs' primary complaint about the Madison Memory Study is that Quincy allegedly conducted various "post hoc" data analyses that included more than 30 "subgroup" analyses. (Compl. ¶ 29.) Yet there is no evidence to support these accusations. In fact, Plaintiffs' experts concede that this argument is based on their own assumptions about how the Madison Memory Study was conducted.

According to one of Plaintiffs' experts, Dr. Wittes, "[a] post hoc analysis is usually defined as an analysis that is done that has not been prespecified and that is done after whoever is doing the analysis looks at the data." (SOF ¶ 140, Wittes Tr. 90:19-25.) There is no evidence in the record that the analyses reported in the Madison Memory Study and on which the Challenged Claims are based (*i.e.*, those relating to participants who scored between a 0 and 2 on the AD8 scale) were "post hoc." But even if they were, there is nothing wrong with either post-hoc or subgroup analyses. First, Quincy's witnesses testified, and Plaintiffs have failed to dispute, that Quincy decided to analyze participant data based on AD8 scores of 0-2 as the study population *before* the Madison Memory Study commenced. (SOF ¶ 107.) Thus, by their very nature, the analyses in question could not be "post hoc" because they were, in fact, prespecified. Second, both of Plaintiffs' experts who reviewed the Madison Memory Study admitted that they had no idea when the "subgroup" analyses in question were planned, when they were conducted, or in

what order they were conducted. For example, Dr. Sano testified that she had not seen any documents setting forth when any subgroup analysis was conducted, and that she *assumed* they were conducted after the "entire study population" was analyzed. (SOF ¶ 141, Sano Tr. 182:11—189:12, 204:18—210:15.) Similarly, Dr. Wittes testified that she did not know when the AD8 0-1 or AD8 0-2 data analyses were planned, and that she did not know when or in what order any of Quincy's analyses were conducted. (SOF ¶ 142, Wittes Tr. 111:8-16, 114:7—116:9.) Thus, Plaintiffs have failed to prove that Quincy conducted any "post hoc" analyses.

Plaintiffs' critiques about Quincy's reliance on data from "subgroups" of participants are equally misplaced and also unfounded. It is undisputed that people who score between a 0 and 2 on the AD8 scale include those who are cognitively normal or those who have minimal cognitive impairment. This is the target market for Prevagen, and was also the target population for the Madison Memory Study as set forth in the protocol and recruitment materials. (SOF ¶¶ 16, 99—101.)

Thus, even assuming that a drug-level randomized clinical trial was required for a dietary supplement (it was not), and assuming further that Quincy did engage in post hoc subgroup analyses (it did not), the Challenged Claims are *still* substantiated by competent and reliable scientific evidence. Plaintiffs have pointed to no law, regulation, or other agency guidance prohibiting the marketing of dietary supplements based on a study's subgroup of participants and, as this Court has already found, use of the subgroup concept "is widely used in the interpretation of data in the dietary supplement field." *Quincy Bioscience*, 272 F. Supp. 3d at 553; *see also* Dkt. No. 34 at 6-7 (discussing the Government's use of subgroup analyses in National Institute of Health's Age-Related Eye Disease Study). Defendants' experts also opined that subgroup

analyses, and even *post hoc* subgroup analyses, are not only common, but are published in peer-reviewed journals. (SOF ¶ 143.)

Subgroup analysis is conducted frequently in clinical trials. In fact, just last year, FDA granted preliminary approval for a new drug called Aduhelm, which is intended for the treatment of Alzheimer's Disease, based on an unplanned analysis of a small subgroup of participants from two separate clinical trials including approximately 3,200 total participants. (SOF ¶¶ 144—145.) Both of those clinical trials were terminated early due to the lack of evidence of efficacy and the severe side effects that were being observed in study participants. (SOF ¶ 146.) Plaintiffs are unable to explain why unplanned subgroup analyses from a *halted* clinical trial is appropriate to support approval of a potentially dangerous and expensive new *drug* under FDA's rigorous new drug regime (which typically requires *two* randomized clinical trials), but *planned* subgroup analyses from a *completed* trial is insufficient to substantiate structure/function claims for a safe and low-cost dietary supplement product, which is not even required to have an RCT in the first place.

While "[t]he FTC plays an important role of ensuring that advertising claims are adequately supported so that consumers may have confidence in a product. Implicit in that role . . . is the expectation of reasonableness." *Basic Rsch.*, 2014 WL 1259647, at *13. Plaintiffs' evaluation of the proffered substantiation for the Challenged Claims simply is not reasonable for multiple reasons: first by requiring a randomized clinical trial in the first instance and ignoring the vast body of scientific evidence supporting the Challenged Claims; second by imposing specific methodological requirements for RCTs that are inconsistent with the FTC Guidance and the opinions of experts in the relevant scientific field; and third by failing to give Quincy *any* notice that it would be subjected to this unpublished, unarticulated standard that is different from what

applies to the rest of the dietary supplement industry. Like in *Bayer*, this Court should reject Plaintiffs' attempt to "reinvent [the] standard through expert testimony" without notice and grant summary judgment in Defendants' favor. *Bayer*, 2015 WL 5822595 at *14.

c. Plaintiffs Failed to Proffer Any Evidence That the Challenged Claims are Likely to Mislead Consumers

As this Court previously noted, Plaintiffs are required to prove that the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstance." *Quincy Bioscience*, 272 F. Supp. 3d at 552 (citing *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 168 (2d Cir. 2016)). Despite this requirement, and the opportunity to do so, Plaintiffs failed to offer any evidence that would establish that any consumers were misled by the Challenged Claims. They failed to proffer the opinion of any marketing or consumer perception experts, and their disclosed experts offer no evidence as to how a consumer would interpret or perceive the Challenged Claims and therefore offer no opinion as to whether the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstance." (SOF ¶¶ 131—136.)[9] This failure of proof alone warrants dismissal of Plaintiffs' claims.

III. PLAINTIFFS' ATTEMPT TO HOLD QUINCY TO A HIGHER SUBSTANTIATION STANDARD VIOLATES DUE PROCESS

As discussed in detail above, Quincy has produced competent and reliable scientific evidence to support its marketing claims about Prevagen. Defendants' experts have all reviewed this evidence in accordance with the FTC Guidance, and independently concluded that Quincy's evidence meets that standard. Plaintiffs' experts' failure to even *consider* anything other than the Madison Memory Study all but confirms that Plaintiffs are applying a heightened standard that is nowhere to be found in the FTC's own Guidance or in DSHEA. (Graham Decl. Ex. T, Sano Report

[9] Plaintiffs' experts did not even *review* Prevagen's advertising and marketing material in connection with their expert reports. (SOF ¶ 131, Berg Tr. 110:7-24, Sano Tr. 50:14-24; Wittes Tr. 38:23—39:2.)

¶¶ 41-42.) Plaintiffs' attempt to impose this new, unpublished standard on Quincy—*retroactively and without notice*—is inappropriate and violates the Due Process Clause of the United States Constitution.

The Supreme Court has made clear that regulated parties cannot be retroactively subjected to new interpretations of applicable regulations without reasonable notice. In *Christopher v. SmithKline Beecham Corp.*, individual pharmaceutical salesmen sued their employers for the failure to compensate them for overtime as required by the Fair Labor Standards Act ("FLSA"). 567 U.S. 142, 152 (2012). The employer responded that the salesmen were "outside salesman" and therefore excluded from the minimum wage and maximum hour requirements set forth in the statute. *Id.* The court agreed, finding that prior DOL regulations confirmed that the salesmen fell within the FLSA's definition of "outside salesmen." *Id.* On appeal, the salesmen argued that the court had failed to consider the DOL's most recent interpretation of the pertinent regulations as announced in various amicus briefs that the DOL had filed in other contemporaneous cases, which they argued was entitled to controlling deference. *Id.* at 152-53. Ultimately, the Supreme Court did not allow for retroactive application of DOL's revised interpretation:

> It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.

Id. at 158-59. The Supreme Court further held that "[t]o defer to the agency's interpretation in this circumstance would seriously undermine the principle that agencies should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires," and "would result in precisely the kind of 'unfair surprise' against which" the Supreme Court has long warned. *Id.* at 156 (collecting cases); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988)

(affirming a finding that retroactive application of an agency rule was improper and noting that "[r]etroactivity is not favored in the law" and that "courts should be reluctant to find" authority to make retroactive rules "absent an express statutory grant").

The Second Circuit is in accord with this well-settled rule. In *Upton v. SEC*, the court considered the propriety of an SEC order that had censured a broker for conduct that violated "the spirit of" an SEC rule despite that the conduct occurred *before* the SEC released a memo publicly condemning the conduct. 75 F.3d 92, 95 (2d Cir. 1996). The Second Circuit vacated the order, holding that, while the SEC is entitled to interpret its own rules expansively, it must "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited." *Id.* (citation omitted); *see also NLRB v. Majestic Weaving, Co.*, 355 F.2d 854, 860 (2d. Cir. 1966) ("[A] decision branding as 'unfair' conduct stamped 'fair' at the time a party acted, raises judicial hackles" particularly where that conduct "might even have been taken in express reliance on the standard previously established"); *Stoller v. Cmty. Futures Trading Comm'n*, 834 F.2d 262, 267 (2d Cir. 1987) (reversing agency order where agency improperly applied an interpretation of its rule adopted through adjudication retroactively as such interpretation "abruptly changed [the agency's] interpretation in the middle of the proceedings" without "appropriate notice").

The FTC's Guidance has not changed since it was issued in or around 1998. And Quincy relied on—and continues to rely on—the FTC Guidance in crafting Prevagen's marketing material. (SOF ¶ 74.) Quincy even engaged outside counsel to review Prevagen labels and advertisements for compliance with the FTC Guidance before using those claims in the marketplace. (SOF ¶ 75.) To penalize Quincy for complying with the very Guidance that the FTC issued—which is still in effect today and is advertised by the FTC as explaining the "how-tos" of dietary supplement marketing—would not only violate Defendants' Due Process rights, but would upend the entire

dietary supplement industry and impose new substantiation requirements that are inconsistent with the FDCA, DSHEA, and the FTC Guidance itself.

IV. PLAINTIFFS ARE NOT ENTITLED TO INJUNCTIVE RELIEF

Even if the Court finds an issue of fact with respect to substantiation, Defendants are independently entitled to summary judgment on Plaintiffs' claims for injunctive relief. The FTC purports to bring its claims for injunctive relief pursuant to Section 13(b) of the FTC Act (15 U.S.C. § 53(b)), which only authorizes the FTC to seek a permanent injunction in a "proper case" where the alleged violations of the FTC Act are ongoing or imminent. But this is not a "proper case" and it is undisputed that Quincy is no longer disseminating, nor does it have any intention of disseminating, the Challenged Claims in the manner alleged in the Complaint. Moreover, both Plaintiffs are required to satisfy the standard for injunctive relief set forth in *United States v. W.T. Grant Co.*, which requires that the conduct to be enjoined be either continuing or likely to recur. 345 U.S. at 633. Because Plaintiffs cannot establish that the challenged conduct is ongoing or likely to recur, Plaintiffs are not entitled to injunctive relief and Quincy is entitled to summary judgment on Plaintiffs' claims.

a. The FTC Lacks Authority to Seek Injunctive Relief

i. Section 13(b) of the FTC Act

Like all administrative agencies, the FTC's enforcement powers are limited to those granted by Congress. *See FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). "As the Court has said many times before, the Commission may exercise only the powers granted it by the [FTC] Act." *Id.*; *see also Bowen*, 488 U.S. at 208; *Arrow-Hart & Hegeman Elec. Co. v. FTC*, 291 U.S. 587, 598 (1934).

When the FTC Act was originally enacted, Section 5 gave the FTC authority to commence an administrative adjudicatory proceeding against a party that "*has been* or *is using* . . . any unfair

or deceptive act or practice in or affecting commerce." 15 U.S.C. § 45(b) (emphasis added); *AMG*, 141 S. Ct. at 1346. If a violation was found, the FTC could issue a cease and desist order and pursue civil penalties in federal court in the event of any future violations. *See United States v. JS&A Grp.*, 716 F.2d 451, 452 (7th Cir. 1983); *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 155 (3d Cir. 2019).

Congress later amended the FTC Act to add Section 13(b), which provides:

> Whenever the Commission has reason to believe—
>
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> > the Commission . . . may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that . . . such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however,* That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further,* That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.

15 U.S.C. § 53(b)(1) (emphases in original).

The different language, and different tenses, used in these two sections of the statute demonstrate that Congress intended the sections to apply to different types of conduct—Section 5 is intended to address past violations, and Section 13(b) is intended to address ongoing or imminent violations. Indeed, as the Supreme Court held just last year, Section 13(b) "focuses upon relief

that is prospective, not retrospective." *AMG*, 141 S. Ct. at 1348. Even before *AMG* was decided, however, courts around the country recognized that "Section 13(b) does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant 'is' committing or 'is about to' commit another violation." *Shire*, 917 F.3d at 160; *see also FTC v. Qualcomm, Inc.*, 969 F.3d 974, 1004 (9th Cir. 2020); *FTC v. Evans Prod. Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985); *FTC v. Elec. Payment Sols. of Am., Inc.*, No. CV-17-02535, 2021 WL 3661138, at *15-17 (D. Ariz. Aug. 11, 2021); *FTC v. Facebook, Inc.*, No. CV 20-3590, 2021 WL 2643627, at *19 (D.D.C. June 28, 2021); *FTC v. AdvoCare Int'l, L.P.*, No. 4:19-CV-715, 2020 WL 6741968, at *5-6 (E.D. Tex. Nov. 16, 2020); *JS & A Grp.*, 716 F.2d at 456 (without Section 13(b), the challenged practices "might continue for several years until agency action is completed").

For example, in *Qualcomm*, the Ninth Circuit considered whether the district court had properly granted an injunction under Section 13(b) based on allegedly anti-competitive agreements that Qualcomm had entered into with Apple, Inc. *See* 969 F.3d at 982. Those agreements, however, expired two years before the FTC filed its complaint and did not pose any current or future threat of anticompetitive harm. *Id.* at 1004. Accordingly, the Ninth Circuit ruled that the district court had no basis for its finding that Qualcomm was "violating or . . . about to violate" the Sherman Act and vacated a previously entered injunction. *Id*.

The Third Circuit similarly rejected the FTC's attempt to enjoin past conduct in *Shire*, where the FTC alleged that the defendant had violated the FTC Act by abusing the FDA's citizen petition process to delay the approval of a competitive generic drug. *See* 917 F.3d at 152. The alleged "abuse" consisted of numerous, allegedly meritless court filings between 2006 and 2012, but the FTC failed to allege any ongoing violations when it filed the complaint in 2017. *See id*. at 152-53. In an attempt to satisfy Section 13(b), the FTC alleged that Shire "is engaged in the

business of . . . developing, manufacturing, and marketing branded drug products" and, "[a]bsent an injunction, there is a cognizable danger that [Shire] will engage in similar conduct causing future harm to competition and consumers." *Id.* at 160. The Third Circuit affirmed the district court's dismissal of the complaint, holding that Section 13(b) cannot be satisfied "by showing a violation in the distant past and a vague and generalized likelihood of recurrent conduct." *Id.* at 159.

ii. Quincy is Not Engaged In, Nor is it "About to" Engage In, the Conduct Challenged in the Complaint

As was the case in *Qualcomm* and *Shire*, the FTC is seeking to enjoin Quincy for past conduct, here specific advertisements and marketing claims that have long disappeared from the marketplace.[10] As explained in the contemporaneously-filed declaration of Todd Olson, Quincy stopped disseminating many of the challenged advertisements and marketing claims *years* before the Complaint was filed and the others shortly thereafter. (SOF ¶¶ 26—38.)

Quincy also has no intention of disseminating any of the claims identified in the *Collins* Settlement in the future. (SOF ¶¶ 54-55.) In November 2020, Defendants entered into a nationwide class action settlement in *Collins v. Quincy Bioscience*, in which they agreed to (even though they did not need to) add one of two Qualifiers concerning the AD8 0-1 and 0-2 subgroups each time they disseminate any marketing impacted by the settlement. (SOF ¶ 45.) The Southern District of Florida granted final approval to the *Collins* Settlement and incorporated the terms of

[10] Other than the advertisements specifically referenced in the Complaint, Plaintiffs have failed to identify that marketing material being challenged in this Action and, instead, have suggested that they are essentially challenging every piece of marketing that Quincy has disseminated since Prevagen hit the market in 2007. The Court previously ordered Plaintiffs to produce a "sampling" of the challenged advertisements that it intended to pursue at trial. (Dkt. 148.) In response, Plaintiffs provided a list of over 1,600 pages of marketing material produced in discovery, as well as various categories of additional documents that are not identified by bates number. (SOF ¶ 153.)

the agreement, including the *Collins* Qualifiers, into a Final Judgment dated November 2020. (SOF ¶ 42.)

Quincy began to incorporate the *Collins* Qualifiers into its advertising and marketing material immediately following approval of the *Collins* Settlement and has no intention of resuming its pre-settlement marketing claims without the *Collins* Qualifiers. (SOF ¶¶ 49-50.) The current marketing for Prevagen includes one of the Qualifiers, which are prominently displayed. (SOF ¶ 52.) These facts are undisputed. The FTC can therefore not establish that any Defendant "is violating" or "is about to violate" Section 13(b) with respect to Quincy's advertising, and this Court should grant summary judgment on that ground.

iii. This Action is Not a "Proper Case" in Which Permanent Injunctive Relief is Available

The FTC also cannot establish that this is a "proper case" for which permanent injunctive relief is even available. The FTC is not entitled to permanent injunctive relief in every case filed under Section 13(b), but rather only in "proper cases" and upon "proper proof." As discussed above, the primary grant of authority in Section 13(b) only permits the FTC to obtain a temporary restraining order or a preliminary injunction when the alleged violations are ongoing or imminent, and it would be in the public interest to restrain said violations "pending the issuance" of an administrative complaint. 15 U.S.C § 53(b). The statute adds two provisos to that authority: First, if an administrative complaint is not filed within a period not to exceed 20 days, the temporary restraining order or preliminary injunction shall be dissolved. *Id.* Second, "in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." *Id.*

Last year, the Supreme Court weighed in on this language:

> Taken as a whole, [Section 13(b)] focuses upon relief that is prospective, not retrospective. Consider the words "is violating" and "is about to violate" (not "has violated") setting forth when the Commission may request injunctive relief. Consider too the words

> "pending the issuance of a complaint," "until such complaint is dismissed," "temporary restraining order," "preliminary injunction," and so forth in the first half of the section. These words reflect that the provision addresses a specific problem, namely, that of stopping seemingly unfair practices from taking place while the Commission determines their lawfulness. . . . ***And the appearance of the words "permanent injunction" (as a proviso) suggests that those words are directly related to a previously issued preliminary injunction.*** They might also be read, for example, as granting authority for the Commission to go one step beyond the provision and ("in proper cases") dispense with administrative proceedings to seek what the words literally say (namely, an *injunction*).

AMG, 141 S. Ct. at 1348 (emphasis added). After *AMG*, other courts have considered what constitutes a "proper case," but the issue is far from settled. For example, in *FTC v. Hoyal & Associates, Inc.*, the Ninth Circuit ruled that a "proper case" is one where there was a reasonable likelihood that the deceptive practices would recur. 859 Fed. App'x 117, 120 (9th Cir. 2021). But if that were the case, every case filed under Section 13(b) would be a "proper case" because the FTC is not permitted to even bring its case in federal court without establishing that the challenged conduct is ongoing or imminent. Because this interpretation would render Section 13(b)'s "proper case" proviso completely superfluous, it is barred by Supreme Court precedent requiring courts to "to give effect, if possible, to every clause and word of a statute." *Duncan v. Walker,* 533 U.S. 167, 174 (2001) (internal quotations omitted); *see also Leocal v. Ashcroft*, 543 U.S. 1, 12 (2004). At a minimum, Congress's use of the phrase "proper case" in a proviso (as opposed to a standalone provision) suggests that permanent injunctions are only available in cases where the FTC has previously sought temporary injunctive relief.[11]

Moreover, it is undisputed (and notable) that the FTC did not seek a temporary restraining order or even a preliminary injunction at any point in time during this litigation. (SOF ¶ 154.) The

[11] *But see FTC v. Am. Future Systems, Inc*., No. CV 20-2266, 2021 WL 3185777, at *1 n.1 (E.D. Pa. July 26, 2021) (holding that "a permanent injunction under Section 13(b) need not be preceded by preliminary injunctive relief" without defining what it means to be a "proper case.").

failure to do so is especially peculiar given that the FTC had issued a civil investigative demand to Quincy before filing this Action and was in receipt of over 200,000 pages of investigative discovery when it filed the Complaint in January 2017. If the FTC thought Quincy's conduct was so egregious that it warranted a suit in district court as opposed to an administrative proceeding, it would have taken advantage of the extra procedural remedies available in Section 13(b) and sought to "immediately halt" Quincy's conduct.

The FTC knows how to frame a "proper case" under Section 13(b). Just last month, the FTC filed an administrative complaint against Intuit, Inc. under Section 5, as well as a District Court complaint for a temporary restraining order and preliminary injunction under Section 13(b) "to prevent interim harm to consumers *during the pendency of an administrative trial on the merits.*" (Graham Decl. Ex. PP, *Federal Trade Commission v. Intuit, Inc.*, No. 5:22-cv-1973 (N.D. Cal. March 28, 2022) at *1; *see also id.* at *30 ¶ 133 (Section 13(b) "authorizes the Commission . . . to seek preliminary relief *to prevent the lawfulness of the conduct of deceptive advertising claims until the Commission can adjudicate the lawfulness of the conduct in an administrative proceeding*.") (emphasis added).).

Having failed to either commence an administrative proceeding *or* seek preliminary relief at the outset of this Action, the FTC should not now be able to obtain permanent injunctive relief many years after commencing its investigation (and this Action) and long after Quincy stopped disseminating the Challenged Claims in the manner alleged in the Complaint. Summary judgment is warranted in Defendants' favor.

b. Plaintiffs Cannot Establish that the Challenged Conduct is Likely to Recur as Required by *United States v. W.T. Grant Co.*

In addition to the FTC's failure to satisfy Section 13(b), neither Plaintiff can establish their entitlement to injunctive relief under *United States v. W. T. Grant Co.*, which requires a party

seeking an injunction to show "that there exists some cognizable danger of recurrent violation, something more than the mere possibility" that the conduct complained of could be repeated. 345 U.S. at 633; *see also FTC v. AbbVie, Inc*, 976 F.3d 327, 381 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 2838 (2021). Numerous courts in this Circuit and elsewhere have held government agencies like the FTC and NYAG to this standard. *AbbVie, Inc.*, 976 F.3d at 380; *Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110 (2d Cir. 1984); *SCM Corp. v. F.T.C.*, 565 F.2d 807, 812-13 (2d Cir. 1977); *FTC v. Shkreli*, No. 20cv00706, 2022 WL 135026, at *44 (S.D.N.Y. Jan. 14, 2022). Plaintiffs cannot satisfy the *Grant* standard for the same reason that the FTC cannot satisfy Section 13(b)—Quincy is no longer disseminating the Challenged Claims in the form challenged in the Complaint and agreed to stop disseminating the claims impacted by the *Collins* Settlement and Final Judgment. Because there is no "cognizable danger" that the conduct Plaintiffs complain of will recur, this Court should enter summary judgment in Defendants' favor and dismiss Plaintiffs' claims for injunctive relief.

c. Plaintiffs are Not Entitled to Injunctive Relief Relating to Advertisements that Comply with the *Collins* Settlement

Finally, Plaintiffs appear to be seeking to enjoin dissemination of Prevagen advertisements that include the *Collins* Qualifiers. This claim fails for four independent reasons.

First, when the Southern District of Florida approved the *Collins* Settlement, it found the terms of the agreement—including the *Collins* Qualifiers —to be "fair, reasonable, and adequate," and incorporated the terms of the agreement into the Final Judgment. Fed. R. Civ. P. 23(e); (SOF ¶ 41.) Quincy immediately began incorporating the *Collins* Qualifiers into all of its marketing for Prevagen that contained the Challenged Claims as set forth in the agreement. (SOF ¶ 52.) Quincy should not be held liable for doing exactly what the Southern District of Florida has permitted it to do. *See In re Santa Fe Natural Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.*, 288 F.

Supp. 3d 1087, 1212, 1233 (D.N.M. 2017) (declining to hold defendant liable for using advertising disclaimer that had previously been agreed to in a settlement agreement with FDA).

Second, there is no allegation or evidence in this case that the *Collins* Qualifiers are false or misleading. None of Plaintiffs' experts even *mention* the *Collins* Qualifiers in their reports, and Sano's definition of the "challenged claims" does not include the *Collins* Qualifiers. (SOF ¶ 131; Graham Decl. Ex. T, Sano Report at 3-4.) Moreover, Plaintiffs' experts admitted that they: (i) did not review any of Quincy's labels, packages, or advertising; (ii) did not know what marketing claims were being challenged in this Action; and (iii) were not offering any opinions about Prevagen's marketing claims or labeling. (SOF ¶ 131.)

Third, it would be fundamentally unfair to permit Plaintiffs to assert a new theory of liability at this late stage of the litigation, given that Plaintiffs did not articulate this theory until earlier this year in response to Defendants' pre-motion letter (and well after fact and expert discovery had closed). (ECF No. 201.); *see Busher v. Barry*, No. 14-CV-4322, 2019 WL 6895281, at *15 (S.D.N.Y. Dec. 18, 2019) (declining to allow "brand-new legal theories . . . on the eve of trial"); *Lyman v. CSX Transp., Inc.*, 364 Fed. App'x 699, 702 (2d Cir. 2010) (holding that the district court did not abuse its discretion when it refused to consider new theories of liability offered in opposition to summary judgment); *Roberts v. Ground Handling, Inc.*, No. 04 CIV. 4955, 2007 WL 2753862, at *5 (S.D.N.Y. Sept. 20, 2007).

And fourth, allowing Plaintiffs to prosecute advertisements that contain one of the *Collins* Qualifiers would be particularly prejudicial here, given that Plaintiffs were on notice of the *Collins* Settlement and had an opportunity to object, but did not do so. (SOF ¶ 46, *Collins* ECF 162-2 ¶¶ 3-4.) Indeed, it was not until November 16, 2020, just one day before the final approval hearing, that Plaintiffs took any action whatsoever regarding the *Collins* Settlement—and even then did not

object to its terms. On that date, they submitted a letter to Judge Goodman in the Southern District of Florida stating that their lack of objection to the settlement "should not be construed . . . as approval or disapproval." (SOF ¶ 47, *Collins* ECF No. 188.) Plaintiffs also appeared at the final approval hearing but did not assert any objection as to any component of the *Collins* Settlement, including the *Collins* Qualifiers. (SOF ¶ 46.) If Plaintiffs truly believed that the injunctive relief provided for in the *Collins* Settlement was insufficient, they should have objected to that relief back in 2020. In fact, CAFA is meant to ensure finality. *See California v. Intelligender, LLC*, 771 F.3d 1169, 1180 (9th Cir. 2014) ("A fundamental precept of common-law adjudication, embodied in the related doctrines of collateral estoppel and res judicata, is that a right, question or fact distinctly put in issue and directly determined by a court of competent jurisdiction . . . cannot be disputed in a subsequent suit between the same parties or their privies. . . . Absent such a guarantee, defendants would have little incentive to agree to any settlement, and plaintiffs would be left with no leverage.").

Plaintiffs should therefore be precluded from arguing, either on summary judgment or at trial, that Prevagen advertisements that contain the *Collins* Qualifiers are false or misleading.

V. NYAG'S CLAIMS FAIL FOR ADDITIONAL, INDEPENDENT REASONS

a. NYAG's Claims Are Preempted or Barred By the Safe Harbor Provision in the GBL to the Extent they Impose Labeling Requirements that are Inconsistent with Federal Law

The NYAG's claims fail for the additional reason that they improperly seek to impose a higher substantiation standard than analogous federal law. This violates the plain language of the FDCA, the governing authority for dietary supplements such as Prevagen, which provides that "no State or political subdivision of a State may directly or indirectly establish" any labeling requirement "that is not identical to the requirement[s]" imposed by the FDCA. 21 U.S.C. § 343-1(a)(5). New York courts have consistently held that state laws governing labeling requirements

must be coextensive with similar requirements imposed by the FDCA and DSHEA (and any resulting guidance), and have rejected attempts by New York plaintiffs to impose standards more stringent than the FDCA and DSHEA. *See In re PepsiCo., Inc., Bottled Water Mktg. & Sales Pracs. Litig.,* 588 F. Supp. 2d 527, 537 (S.D.N.Y. 2008) (dismissing plaintiffs' state consumer protection law claims based on alleged mislabeling as they were "premised on requirements that are not parallel to those imposed by federal law" under the FDCA); *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *9 (S.D.N.Y. Sept. 9, 2015) (dismissing plaintiffs' claims because they attempted to impose state law requirements which went beyond the FDCA's labeling requirements); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376-77 (S.D.N.Y. 2014) (holding that state law could not impose labeling requirements beyond those promulgated under the FDCA); *see also Greenberg v. Target Corp.,* 402 F. Supp. 3d 836, 840 (N.D. Cal. 2019), *aff'd* 985 F.3d 650 (9th Cir. 2021) (granting motion for summary judgment dismissing state law claims as they were predicated on labeling requirements beyond those required by the FDCA); *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 106-09 (D.D.C. 2006), *aff'd*, 508 F.3d 11 (D.C. Cir. 2007) (holding that certain claims sought to impose requirements beyond federal regulations and were therefore pre-empted by § 343-1(a)(1)).

Indeed, this requirement to maintain co-extensive regulatory requirements with the FDCA and DSHEA is expressly set forth in the GBL itself. General Business Law §§ 349(d) and 350 contain a safe harbor, establishing as a "complete defense" that the complained-of practices are permitted by federal law. *See Manchanda v. Educ. Credit Mgmt. Corp*., No. 19 CIV. 5121, 2022 WL 137885, at *2 (S.D.N.Y. Jan. 14, 2022) (dismissing GBL § 349 claim where collection costs on student debt were within limits imposed by the federal Department of Education, and noting that where alleged conduct "[is] permitted by federal law, there is no [state law] violation");

Izquierdo v. Mondelez Int'l, Inc., No. 16-CV-04697, 2016 WL 6459832, at *4 (S.D.N.Y. Oct. 26, 2016) ("New York law expressly incorporates the standard imposed by the FDCA. It provides that anything that complies with federal law and regulations *per se* complies with state law."); *see also Colella v. Atkins Nutritionals, Inc*., 348 F. Supp. 3d 120, 134-37 (E.D.N.Y. 2018) (dismissing GBL claims as being both pre-empted and within the GBL's safe harbor provisions because the labels complied with the relevant FDCA regulations); *Am. Home Prod. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (noting that the 349(d) and 350-d safe harbors are broadly construed to apply to both FTC and other applicable federal regulations).

The same result is warranted here. To the extent the NYAG is attempting to impose a higher standard on Prevagen's marketing claim than is already required by federal law, such claims are preempted and/or fail because of the safe harbor provision of the GBL.

b. The NYAG Is Not Entitled To Restitution

It is well-settled that government agencies cannot pursue restitution on behalf of individual consumers that have been released by a class settlement. *See In re Baldwin-United Corp*., 770 F.2d 328, 339 (2d Cir. 1985); *IntelliGender, LLC*, 771 F.3d at 1172. Thus, the NYAG is not entitled to recover restitution on behalf of New York residents who purchased Prevagen prior to the *Collins* Settlement, and Defendants are entitled to summary judgment accordingly.

Baldwin-United involved a consolidated, multi-district class action against various broker-dealers who sold certain securities. 770 F.2d at 331. The class action settled, and the Southern District of New York subsequently enjoined various state attorneys general from commencing any action on behalf of class members against the defendants seeking money damages arising out of the sales of those same securities. *Id.* at 334. The Second Circuit affirmed, finding that the injunction unambiguously "bar[red] the states from undertaking actions of a representative

character seeking additional restitution for state residents who purchased" the securities at issue. *Id.* at 339. The rationale for such a rule is sound:

> The success of any federal settlement [is] dependent on the parties' ability to agree to the release of any and all related civil claims the plaintiffs had against the settling defendants based on the same facts. If states or others could derivatively assert the same claims on behalf of the same class or members of it, there could be no certainty about the finality of any federal settlement.

Id. at 337. Absent such protection against future litigation, "the finality of virtually any class action involving pendent state claims could be defeated by subsequent suits brought by the states asserting rights derivative of those released by the class members." *Id*. at 336.

The Ninth Circuit came to the same result in *IntelliGender*, in which the Central District of California approved a nationwide class action settlement providing monetary relief to class members. 77 F.3d at 1175. The defendant then sought to enjoin the State of California—which had failed to object or otherwise participate in the settlement approval process despite being on notice of the settlement as required by CAFA—from pursuing restitution claims against the defendant on behalf of California consumers. *Id.* at 1175-76. While the district court initially denied the requested injunction, the Ninth Circuit reversed: "[I]t goes without saying that the courts can and should preclude double recovery by an individual. To the extent that the State seeks restitution for individual members of the . . . certified class, it may be enjoined from doing so." *Id.* at 1179 (internal quotations omitted). The Ninth Circuit reasoned that if the rule were otherwise, "defendants would have little incentive to agree to any settlement, and plaintiffs would be left with no leverage. . . . Allowing the State's claims for restitution to go forward . . . would undermine this central guarantee of our legal system and undercut CAFA's purpose of increasing the fairness and consistency of class action settlements." *Id.* at 1180-81; *see also Applied Card Sys.,* 11 N.Y.3d at 109 (holding that "res judicata effect should be granted to a prior nationwide

class action settlement, thereby precluding the Attorney General from recovering certain restitution"); *Silvar v. Comm'r of Labor of N.Y.*, 175 A.D. 3d 95, 104 (1st Dep't 2019) (holding that res judicata barred the Commissioner of Labor for the State of New York from pursuing wage claims that had been released as part of a prior class action settlement); *FTC v. AMREP Corp*., 705 F. Supp. 119, 125 (S.D.N.Y. 1988) (granting summary judgment and dismissing the FTC's claim for restitution on behalf of consumers that participated in prior class action settlement).

This Action presents substantially identical facts to those at issue in *Baldwin* and *IntelliGender*. In November 2020, Defendants resolved several nationwide class actions challenging the same marketing claims Plaintiffs challenge in this Action. Under the *Collins* Settlement, any person who purchased Prevagen in the United States since it became available for sale in 2007 was entitled to obtain monetary relief and they were provided with injunctive relief. (SOF ¶ 43.) In exchange, class members released Defendants "from all claims, demands, actions, and causes of action of any kind or nature whatsoever" that they "ever had, now have, may have, or hereafter can, shall or may ever have against the [Defendants] in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the Action." (SOF ¶ 44, *Collins* Settlement Agreement at 6, 12.) The Southern District of Florida found that the terms of the *Collins* Settlement were "fair, reasonable, and adequate" and granted final approval to the settlement in November 2022. (SOF ¶ 41.)

There can be no dispute (and the NYAG appears to concede[12]) that the release in the *Collins* Settlement bars the NYAG's current claim for restitution on behalf of consumers who purchased

[12] In response to Defendants' pre-motion letter, the NYAG stated that "[t]he settlement class in [*Collins*] does not include consumers who were harmed by Defendants' deceptive acts and practices from July 22, 2020 to today, and thus the NYAG is not precluded from obtaining relief *for them*." (emphasis added) (ECF 202 at 3). Moreover, to the extent the NYAG appears to be pursuing restitution on behalf of New York consumers who purchased Prevagen after

Prevagen prior to the *Collins* Settlement. *See AMREP Corp.*, 705 F. Supp. at 125 ("[P]rivate parties can release the right to have an action brought on their behalf by a [government agency] representative."). The relevant inquiry is whether "the government is suing for the same relief *already pursued* by the plaintiff." *IntelliGender*, 77 F.3d at 1180 (first emphasis added). This is plainly the case here. In *Collins*, the plaintiffs sought to recover (and, through the settlement, were provided with an opportunity to recover) monetary relief as a result of allegedly false advertising and marketing claims for Prevagen. In this Action, the NYAG is seeking restitution (monetary relief) on behalf of those *same* consumers as a result of the *same* advertising. It cannot do so.

Moreover, like in *IntelliGender*, the NYAG was notified of the *Collins* Settlement in accordance with CAFA (SOF ¶ 46, Collins ECF 162-2), ***but failed to take any action to object to its terms***. (Section F, *supra*.) If the NYAG believed that the restitution provided for in the *Collins* Settlement was insufficient, it should have objected to that relief in *Collins*.

To allow the NYAG's claim for restitution to go forward now would result in a double recovery for those same New York consumers who participated in the *Collins* Settlement. Quincy is therefore entitled to summary judgment on the NYAG's pre-Settlement claim for restitution. Moreover, it is precluded from recovering any restitution on behalf of New York residents as a result of the post-*Collins* Settlement advertisements or marketing because it has not alleged in this action, or provided any proof, that any such advertisements or marketing are false or misleading.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion and enter summary judgment in Defendants' favor with respect to each of Plaintiffs' claims.

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the *Collins* Settlement, such claims are also barred because Prevagen's post-settlement marketing materials includes the qualifying language required by the *Collins* Settlement and approved by the Southern District of Florida. (*See* Section F, *supra;* SOF ¶ 51.)

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